

DOCKET NO: 4278/PCT
INVENTORS: Oliver ROEHE
Horst LAUBE
Martin MATTHAEUS

LITERAL TRANSLATION OF PCT INTERNATIONAL APPLICATION
PCT/DE00/03310 AS FILED ON SEPTEMBER 22, 2000

Method and Device for Inserting Implants Into Human Organs

The invention relates to a method for the insertion of implants into human organs, especially for the installation of biological as well as artificial heart valves, as well as an apparatus for carrying out a method of this kind.

In order to prevent, or at least reduce to a minimum, the immune reaction of the human organism with respect to implanted organ parts which are foreign to the body, and in order to prolong the long term durability or service life of special biological implants, it is an already known measure to coat the surfaces of the implants with living cells before the implantation into the human organism. Ideally, homologous cells, i.e. the body's own cells, or cells identical thereto, are concerned in this context. In that regard, the coating of the implants can be carried out in an especially advantageous manner in an apparatus as is described in the German Patent 198 34 396 C1[] and corresponding U.S. Patent 6,214,407.

In any event, it is important in this procedure, that the vital cell layer of the thusly prepared organ parts, which are especially biological as well as synthetic or artificial heart

valves, is not destroyed by the surgical implantation technique, or are implanted into the human body, in this case into the recipient heart, in the shortest possible operation time after the completed coating, so that the applied cells do not already
5 begin to die off before the successful completion of the transplantation.

✓ SUMMARY OF THE INVENTION

An object of the invention is to develop a method of the above initially described type in such a manner so that it is ensured that artificial or biological organ parts, especially those that have been subjected to a cell coating before the implantation, can be inserted into the recipient organ in a short time and in an irritation-free manner to the extent possible. Moreover, it is an object of the invention, to provide an apparatus for carrying out a method of this type.

The invention achieves the first object by a method in which the implant is provided with an adapter element, a receiver element adapted or matched to the adapter element is sutured together with the recipient organ, and the adapter element is connected with the receiver element. The further object is achieved according to the invention by an apparatus, in which both the
20 receiver element as well as the adapter element are embodied with a ring shape and are respectively provided with a flange-like shoulder or projection.

In an advantageous further development of the invention, it is
25 provided in this context, that the connection of adapter element

and receiver element is achieved via a fastener, that is embodied as a bayonet lock and essentially only requires a rotation or turning. Moreover, this fastener is equipped with self-locking guide elements in an advantageous embodiment of the invention.

5 Therewith the invention has the advantage, that the elements that are to be connected with one another cannot be loosened or released from one another in an automatic or self-acting manner, also in connection with a pulsating internal pressure, as it exists in connection with the heart. By means of elastic seal edges, a sufficient seal to the inside and to the outside is ensured simultaneously. On the other hand, a loosening or releasing of the connection is also still possible after several years of installed use, as the case may be, with the aid of a specially fitted disassembly tool. Thereby it is possible to fabricate the adapter element as well as the receiver element of a sterilizable body-compatible synthetic material. Finally, the adapter element provided in the apparatus according to the invention has the advantage that it can, without problems, be coated with living cells, together with the organ part that is to be
20 implanted, preferably a biological as well as artificial heart valve, in the apparatus described in the German Patent 198 34 396 Cl[?] and the corresponding U.S. Patent 6,214,407.

BRIEF DESCRIPTION OF THE DRAWINGS

In the following, the invention shall be described in further detail in connection with an example embodiment illustrated as
25 a general principle in the drawing. Therein:

Fig. 1 shows a top plan view onto a receiver element,

Fig. 2 shows the element according to Fig. 1 in a partially sectioned side illustration,

Fig. 3 shows an enlarged detail illustration III of the arrangement according to Fig. 2,

Fig. 4 shows a partially sectioned side illustration of an adapter element,

Fig. 5 shows an enlarged detail illustration V of the arrangement according to Fig. 4, and

Fig. 6 shows an enlarged detail illustration of the threading in the screwed-together position.

DETAILED DESCRIPTION OF A PREFERRED EXAMPLE EMBODIMENT OF THE INVENTION

The receiver element 1 illustrated in the Figures 1 to 3 essentially consists of a ring that is provided with a flange-like shoulder or projection 2 and that has a threading 3 on its outer surface. In the presently illustrated example embodiment, in which the receiver element 1 serves for the implantation of an artificial heart valve, this ring, with an outer diameter of 29 mm and a width of about 3 mm, comprises a four-fold sharp V-thread with a pitch of 8 mm and a web width of 1 mm. In the presently illustrated example embodiment, the web height amounts to 0.5 mm. The flange 2 is provided with a set of bored through holes 4, which comprise a diameter of 0.4 mm in the presently

illustrated example embodiment, and which serve for the suturing with the recipient organ, in this case the recipient heart.

The adapter element 5 illustrated in the Figures 4 and 5 is similarly embodied as a ring with a flange-like shoulder or projection 6, whereby the flange is again provided with bored holes 7. In its interior, the adapter element 5 is provided with an internal threading 8, of which the dimensions are adapted or matched to the external threading of the receiver element 1. Both elements 1 and 5 consist of a sterilizable body-compatible synthetic or plastic.

In connection with the insertion of an artificial heart valve, before the actual operation, this valve is first connected with the adapter element 5, in this case being sutured together, and together with the adapter element is coated on the surface with living cells in an apparatus especially embodied for this purpose. Then, for beginning the transplantation operation, first the receiver element 1 is sutured into the heart, and in the following step the coated combination of heart valve and adapter element 5 is inserted into the receiver element 1, and both components are mechanically securely connected with one another by relative rotation or turning by about 30 angular degrees.

✓ ABSTRACT OF THE DISCLOSURE

, such as a biological or artificial heart valve

✓ In a method for ^{inserting an} [the insertion of] implants ^a into [human organs],
✓ [especially for the implantation of biological as well as artificial heart valves], first the implant is provided with an adapter
✓ element, then a receiver element that is [matched or] adapted to ^{fit}

✓ the adapter element is sutured to the recipient organ, and finally the adapter element is connected ^{to} [with] the receiver element.

✓ ^{The} Receiver element and ^{the} adapter element, are embodied with ^{each} a ring
✓ shape ^d and are provided with ^{matched interengageable} threadings [that are matched to one

10 another]. They are connected with one another by ^{relative} [turning or]

✓ rotation via a self-locking bayonet lock. Before ^{being connected to} [the connection
✓ with] the receiver element, the implant together with the adapter

✓ element are coated with living cells. Both the receiver element
[as well as] ^{and} the adapter element [are] respectively ^{have} [provided with]

15 [flange-like projections which, on their part, comprise constructive] ^{flanges that include} elements for [suturing] together with the recipient organ or
the implant. ^{being sutured}

204420-ED264001